



Identifying criteria for environmental risk assessment models at different stage-gates of nanomaterial/product innovation considering requirements of various stakeholders

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Introduction

The caLIBRAte project

Generally, existing REACH compliance models are not well-suited or validated for the risk assessment of manufactured nanomaterials (MNM).

The caLIBRAte project aims to develop a “systems-of-systems” (SoS) to assist in the risk assessment of MNMs.

This SoS will be based on a suite of tested and calibrated nano-specific risk prioritization and control banding tools. Our work will leverage more than a decade of nanosafety research and resources to develop models for next generation nano-risk governance framework.

More information at the official website:
<http://www.nanocalibrate.eu/home>

Aim & Method

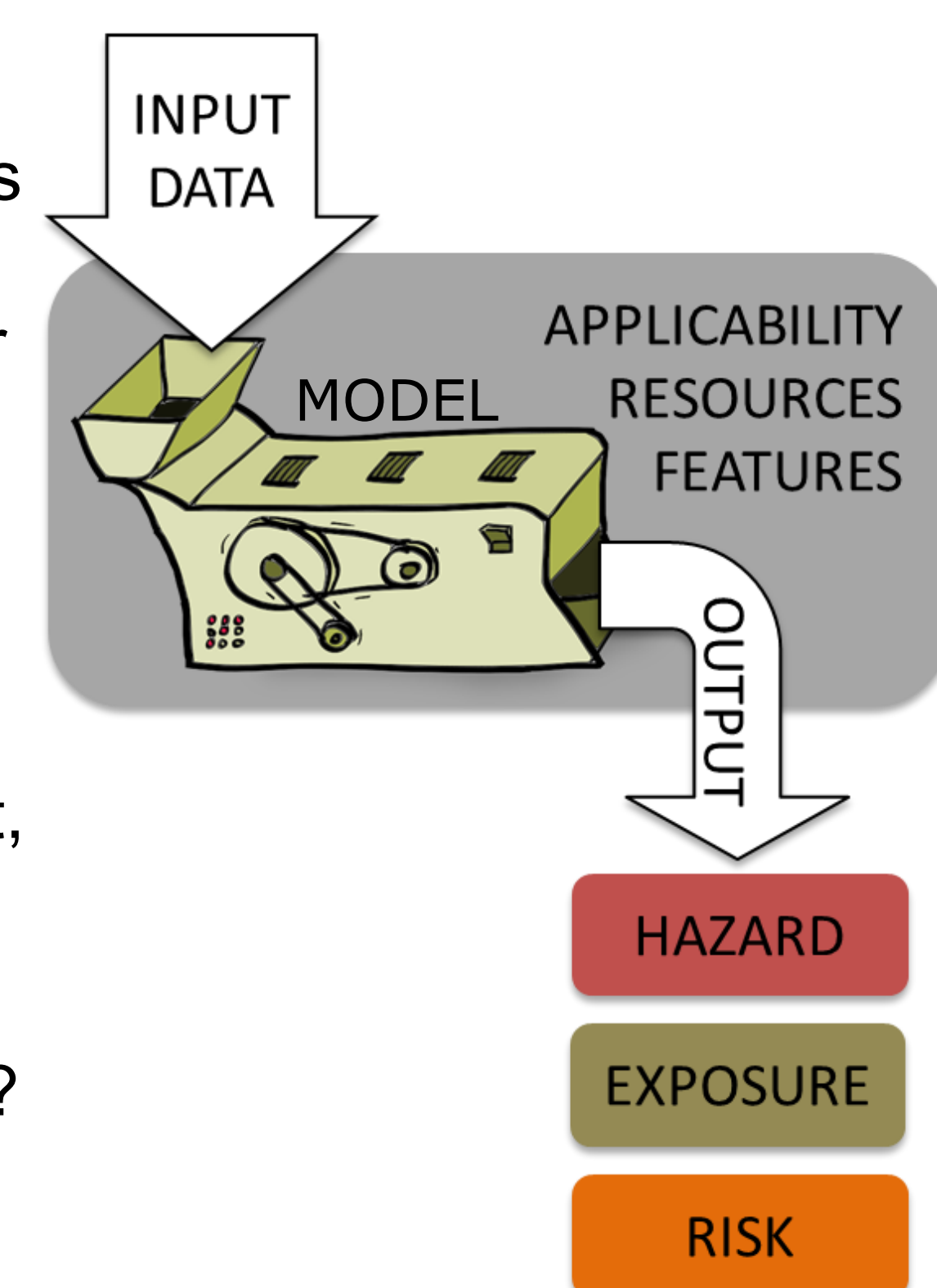
What do stakeholders need from models?

An initial task was to identify various stakeholders’ requirements for environmental risk assessment (ERA) models at different stages in the innovation process of MNM-products. The Cooper stage-gate model was applied for this purpose.

Questionnaires were sent to different stakeholders and considered by caLIBRAte partners as well. The main focus points in questionnaires were:

1. Which *output data* for hazard, exposure and risk assessment, respectively, are needed from models?
2. What are the application-limiting factors of ERA models in terms of user resources required, and model features provided?

Gaps in available *input data* required for the model to run, are identified in other caLIBRAte tasks.



Stakeholders



Key points of stakeholders

- The stage-gate approach is not applied by all, or different versions are applied
- The mid-stages are most important (*R&D, Testing & Validation, and Launch*)
- No testing or regulatory compliance work is done at earlier stage-gates
- Confidentiality is very important, so SoS tool needs stand-alone format option
- Regulatory compliance essential, as it is main driver for risk-related work
- Hazard is generally considered at earlier stage-gates than exposure
- Regular update of SoS needed, which requires adaptation options and link to updated databases
- Simplicity of the SoS is essential - especially SMEs lack expertise/resources

Key points of caLIBRAte experts

- QSARs may help identify “red flags” for MNM hazards early in the innovation process, before large costs are spent – and to estimate exposure levels as experimental exposure data are scarce
- Safety-by-design approaches may assist to foresee and prevent risks related to MNMs and MNM-enabled products early in the product innovation
- Include foreseeable changes of regulatory frameworks relating to the fate and ecotoxicity testing of MNMs into the SoS – for example use of different units (dose-metrics) or consideration of spatial and temporal dynamics of MNM behavior

The next steps...

The criteria and requirements for ERA models identified by caLIBRAte experts and stakeholders will provide basis for further development of decision support tools and risk assessment models applicable to different stakeholders.

Currently, existing environmental hazard, exposure and risk assessment models are being evaluated against the identified requirements, and their applicability at the different product innovation stage-gates are being assessed.

Later, the models will be refined to accommodate the needs of stakeholders and enable risk assessment of MNMs and products within the SoS framework being developed.



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